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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,813	01/03/2007	Stephen John Ralph	DAVI271.001APC	5240

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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06/10/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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efiling@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/575,813	Applicant(s) RALPH, STEPHEN JOHN	
	Examiner Mark Navarro	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11, 14-17 and 19-52 is/are pending in the application.
- 4a) Of the above claim(s) 46-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 11 14-17 19-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment filed April 15, 2010 has been received and entered. Claims 8-10, 12-13, 18, and 53-64 have been cancelled. Accordingly, claims 1-7, 11 and 13-17 and 19-52 are pending in the instant application, of which claims 46-52 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-9, 11 and 13-45 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is withdrawn in view of Applicants amendment.
2. The rejection of claims 1-9, 11 and 13-45 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "corresponds to at least a portion of the target antigen" is withdrawn in view of Applicants amendment.
3. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite vague and indefinite in the recitation of "synthetic or semisynthetic analogue thereof" is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1-9, 11 and 13-45 under 35 U.S.C. 102(b) as being anticipated by Figdor et al is withdrawn in view of Applicants amendment.

5. The rejection of claims 1-7, 11, 14-17, and 19-45 under 35 U.S.C. 102(b) as being anticipated by Nedwin et al is maintained.

Applicants are asserting that lectin is not an immune modulating agent as claimed in the present application because it is neither a target antigen or part of the target antigen that elicits an immune response, an antigen binding molecule, or an immune modulating cell that modulates an immune response to the target antigen. Applicants further assert that Example 7 of Nedwin is to test the suitability of lectin in vivo, and therefore does not disclose a method or composition for modulating an immune response as presently claimed.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants assert that lectin is not an immune modulating agent as claimed

Art Unit: 1645

in the present application because it is neither a target antigen or part of the target antigen that elicits an immune response. However, Applicants are respectfully directed back to their own claim language. Specifically, the limitation of a target antigen, which Applicants will hopefully appreciate has no structural limitations (e.g., SEQ ID NO: 1, etc). Furthermore, Applicants are directed to section D of Nedwin, which discloses of eliciting antibodies against lectin. Consequently, if an antibody can be elicited against the lectin it meets the limitation of "immune modulating agent" and is clearly a target antigen/part of the target antigen that elicits an immune response.

Finally, Applicants assert that Example 7 of Nedwin is to test the suitability of lectin in vivo, and therefore does not disclose a method or composition for modulating an immune response as presently claimed. Applicants assertion that Nedwin does not disclose a "method" for modulating an immune response is simply not germane to claims reciting a "composition." Applicants final argument that Nedwin does not disclose of the composition being used to modulate an immune response is noted, however this is nothing more than an intended use statement. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999).

Art Unit: 1645

The claims are directed to a composition for modulating an immune response to a target antigen, comprising a soluble non-metabolizable carbohydrate or a soluble non-metabolizable carbohydrate containing molecule selected from the group consisting of monosaccharides, disaccharides, larger saccharides, synthetic carbohydrates, glycopeptides, N-acetyllactosamine derivatives, modified polysaccharides, starburst dendrimers and glycopolymers, and an immune-modulating agent selected from the group consisting of the target antigen, a part of the target antigen that elicits an immune response against the target antigen, an antigen binding molecule that is immunoreactive with the target antigen and an immuno-modulating cell that modulates an immune response to the target antigen, wherein the carbohydrate or carbohydrate containing molecule and the immune-modulating agent are not conjugated to each other, and wherein the immune modulating agent produces a greater immune response in the presence of said carbohydrate or carbohydrate containing molecule than in the absence of said carbohydrate or carbohydrate containing molecule.

Nedwin et al (US Patent Number 5,587,460) disclose of a composition containing purified 14 kDa lectins and thiodigalactoside. (See Example 7).

Given that Nedwin et al disclose of a composition comprising a lectin interactive agent (thiodigalactoside) and an immune-modulating agent (14 kDa lectins), the disclosure of Nedwin et al is deemed to anticipate the instantly filed claims.

For reasons of record, as well as the reasons set forth above this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
June 6, 2010